

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

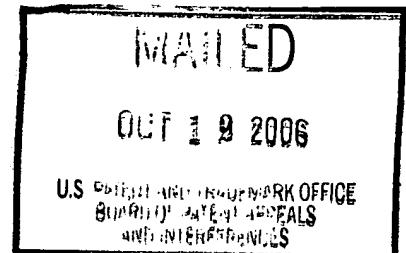
UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte ASTRID KLEEN, ANDREA SAETTLER,
HORST HOEFFKES, RALF OTTO, and OLIVER BRABAENDER

Appeal No. 2006-3063
Application No. 10/088,432

ON BRIEF



Before GREEN, LINCK, and LEBOVITZ, Administrative Patent Judges.

LEBOVITZ, Administrative Patent Judge.

DECISION ON APPEAL

This appeal involves claims to a process for restructuring keratin fibers. The Examiner has rejected the claims as obvious. We have jurisdiction under 35 U.S.C. § 134. We reverse, but enter new grounds of rejection for all appealed claims.

Background

Hair care treatments can damage the hair. Specification, page 1, lines 1-10. Bleaching, coloring and tinting, wave formation, and other hair styling methods can adversely affect hair structure. Id. To counteract this damage, the instant application provides processes for restructuring keratin fibers, a structural component of hair, by applying a transglutaminase enzyme and an "active substance" which is a substrate for

the enzyme. Id., page 1, lines 19-23; page 2, lines 6-9. The active substance is crosslinked to keratin fibers (e.g., hair) by the activity of the transglutaminase. This process “restructures” the keratin fiber, “restoring the natural strength of the hair,” and improving its luster and feel. Id., page 1, line 22-page 2, line 5. Examples of active substances include proteins, protein hydrolyzates, collagen, keratin, and soya proteins. Id., page 3, lines 15-25.

Discussion

Claim construction

Claims 13-27 are on appeal. We will focus on claim 13 as representative of the appealed claims.

13. A process for restructuring keratin fibers comprising applying to keratin fibers
 - (a) at least one enzyme having transglutaminase activity; and
 - (b) at least one substance having substrate activity for the enzyme.

Keratin fibers “in the context of the invention are understood to include pelts, wool, feathers and in particular human hair.” Specification, page 2, lines 14-15. Restructuring the fibers is described to be “a reduction in the damage done to keratin fibers” by various treatments and conditions, including, oxidative coloring of hair, frequent washing, blow drying, and UV light. Id., page 1, line 25-page 2, line 5. Transglutaminases are enzymes which catalyze the reaction of an amino acid with an alkylamine. Id., page 2, lines 16-22. A “substance having substrate activity” for the enzyme is “any substance which can be added onto the hair by the transglutaminase.” Id., page 3, lines 8-10. Examples of active substances include proteins, protein hydrolyzates, collagen, keratin, and soya proteins. Id., page 3, lines 15-24. Thus, the

claim is drawn to a method of reducing damage to keratin fibers, such as human hair, by the addition of a protein to the hair using the activity of a transglutaminase.

Obviousness under 35 U.S.C. § 103

Bernard

Claims 13, 15-20, and 24-26 stand rejected under 35 U.S.C. § 103(a) as obvious over Bernard¹.

The Bernard patent relates to compositions for promoting desquamation of the skin, the process in which excess skin is peeled off. Brief, page 6, paragraph 2. The epidermis contains an outer layer of corneocytes that is responsible for the barrier function of the skin. Bernard, column 1, lines 45-50. The corneocytes tightly adhere together. Id., column 2, lines 18-30. Bernard describes the isolation of cathepsin L type cysteine proteases that are capable of destroying the intercorneocyte junctions. Id., column 3, lines 40-47; column 4, lines 53-57; column 5, lines 45-52. Applying them to the skin surface promotes desquamation. Id., column 1, lines 15-20. Compositions containing the proteases are described as useful for treating pathological conditions associated with abnormal desquamation and for cosmetic purposes. Id., column 5, line 52-column 6, line 7. Other agents can be included, as well, including protease activators (id., column 6, line 18-column 7, line 32) and other additives (id., column 8, line 49-column 9, line 26). Transglutaminases are listed as an exemplary protease activator. Id., column 6, lines 52-67. The compositions can be formulated as various

¹ Bernard et al. (Bernard), U.S. Pat. No. 6,274,364, issued Aug. 14, 2001.

cosmetics, including skin and hair care products. Id., column 8, line 15-25.

According to the Examiner, Bernard teaches a hair treating composition containing a transglutaminase and a substrate for it, but “does not require such a treating composition with sufficient specificity to constitute anticipation.” Answer, page 3. However, the Examiner stated that it would have been obvious to the ordinary skilled worker to apply a composition to keratin fibers for the reason that:

such a composition that comprises transglutaminase enzymes and substance having substrate activity of protein hydrolyze falls within the scope of those taught by Bernard et al. Therefore, one of ordinary skill in the art would have had a reasonable expectation of success, because such a composition is expressly suggested by Bernard et al disclosure and therefore is an obvious formulation.

Answer pages 3-4.

Appellants raised numerous objections to the rejection. They argued that the Examiner had improperly focused on the obviousness of the enzyme formulation recited in the claim, when it was a method of using that was being claimed. Brief, page 5. Appellants also contended that the Examiner did not properly identify the motivation “to pick various components taught in the Bernard reference and employ such components so as to arrived at Appellant’s claimed process.” Id., page 6, paragraph 3; page 7.

Most inventions are put together from parts which are found in the prior art. In re Kahn, 441 F.3d 977, 986, 78 USPQ.2d 1329, 1335 (Fed. Cir. 2006). For this reason, when setting forth a proper rejection under 35 U.S.C. § 103, the starting point is usually a description of where the elements of the claimed invention are identified in the prior art. However, a map of where these elements reside in the prior art is not sufficient to defeat the invention’s patentability. The Examiner must also articulate a reason that would have led the skilled worker to have made the claimed invention or to have

combined the claimed elements in the way they are arranged in the claims. Id. Although it is not necessary that the reason be explicitly stated in the prior art, the Examiner must explain why “the combined teachings, knowledge of one of ordinary skill in the art, and the nature of the problem to be solved as a whole would have suggested [the claimed invention] to those of ordinary skill in the art.” Kahn, 441 F.3d at 987-988, 78 USPQ2d at 1336.

In this case, we can find where the elements recited in claim 13 are located in the prior art reference by Bernard, but we do not see a clear reason why a person of ordinary skill in the art would have combined them in the manner required by the claims. The Examiner pointed to where a transglutaminase and its substrate are disclosed in Bernard (Answer, page 6, paragraph 3), but failed to articulate a reasonable teaching or suggestion for picking them from the disclosure to have arrived at the claimed subject matter.

Bernard teaches a composition containing a cathepsin protease. A protease activator is optionally present in the composition, but the choice of a transglutaminase as the activator requires its selection from a list. Bernard, column 6, line 18-column 7, line 32. To meet all the claim limitations, a transglutaminase substrate must also be present. The Examiner argued that enzyme substrates, such as protein hydrolysates, are disclosed in Bernard at column 9, lines 17-22 in combination with transglutaminases. Answer, page 6, paragraph 3. Our difficulty with this argument is that the Examiner has ignored the context in which “proteins or protein hydrolysates” are disclosed. Bernard’s primary focus is on L type cysteine proteases which, when in composition form, can contain other additives. Bernard, Abstract; column 8, lines 49-

50. From column 8, line 49-column 10, line 15, Bernard discloses a long list of additives that can be combined with the L type cysteine proteases, and optionally a protease activator. This list includes "proteins or protein hydrolysates." Apparently, because a second selection step is required to pick "proteins or protein hydrolysates," the Examiner did not consider the claimed subject matter to be anticipated, but instead viewed it obvious in view of Barnard's patent. But characterizing the rejection as one of "obviousness," did not end his job. There still must be a statement to explain why the selection of "proteins or protein hydrolysates" would have been obvious in view of the prior art, the knowledge of the skilled worker, and the nature of the problem. Kahn, 441 F.3d at 987-988, 78 USPQ2d at 1336. This is where the rejection falls. The claims recite a combination of a transglutaminase and a substance having substrate activity for it. After having picked the transglutaminase from Bernard's list of preferred protease activators, there must be a clear suggestion to combine it with the protein substrates. With no emphasis or examples that would have lead the person of ordinary skill in the art to have chosen "proteins or protein hydrolysates" from the list of possible additives, it is our view that obviousness of the claimed subject matter is precluded because Bernard does not reasonably suggest choosing it in combination with a transglutaminase. Thus, on the record before us, we do not find that the Examiner has provided adequate evidence to establish a prima facie case of obviousness. This rejection is reversed.

Bernard in view of McDevitt

Claims 14, 21-23, and 27 stand rejected under 35 U.S.C. § 103(a) as obvious over Bernard in view of McDevitt².

McDevitt was further relied upon by the Examiner for its teaching of calcium-independent transglutaminases as required in claims 14 and 27, and for the order and timing of the application of the transglutaminase/active substance recited in claims 21-23. We do not find that the addition of McDevitt to the rejection addresses the aforementioned deficiency in the adequacy of the case of prima facie obviousness. Consequently, this rejection is also reversed.

New Grounds of Rejection

Under the provisions of 37 C.F.R. § 41.50(b), we enter the following new grounds of rejection.

Richardson

Claims 13, 15-18, 21, and 23-26 are rejected under 35 U.S.C. § 102(b) as being anticipated by Richardson³.

The background section of the instant application characterizes Richardson as describing a “composition for treating human skin, hair or nails with which active substances containing a primary amino group are added onto the glutamine components of the skin, hair or nails by transglutaminase.” Specification, page 3, lines 2-5. We find that this disclosure anticipates certain claims of the instant application.

Anticipation requires a showing that each element of the claim is identifiable in a

² McDevitt et al. (McDevitt), U.S. Pat. No. 6,051,033, issued Apr. 18, 2000.

³ Richardson et al. (Richardson), U.S. Pat. No. 5,490,980, issued Feb. 13, 1996.

single reference. See, e.g., Perricone v. Medicis Pharm. Corp., 432 F.3d 1368, 1375, 77 USPQ2d 1321, 1325 (Fed. Cir. 2005). Richardson describes a composition comprising a transglutaminase⁴ and an active ingredient which contains an alkyl amine group which is a substrate for the enzyme⁵. Richardson, column 1, lines 5-10; column 2 (“Summary of the Invention”); column 10, lines 52-58. The composition can be applied to hair and utilized as a conditioner for “the treatment of dry, unmanageable hair.” Id., column 1, line 8; column 2, line 61; column 7, lines 45-55; column 18, Example 5; column 19, lines 65-67. These elements meet the requirements of process claims 13 and 18.

For claim 24, giving the phrase “setting keratin fibers” its broadest reasonable interpretation (In re Bond, 910 F.2d 831, 833, 15 USPQ2d 1566, 1567 (Fed. Cir. 1990)), we construe it to mean any step in which the keratin fibers (e.g., hair) are arranged or styled, including combing, brushing, or leaving the conditioned fibers to dry after application of the transglutaminase. Because Richardson teaches that transglutaminase may be utilized to condition hair, it logically follows that the hair would at least be dried after its application, if not combed, brushed, or otherwise arranged. If “the disclosure is sufficient to show that the natural result flowing from the operation as taught would result in the performance of the questioned function, it seems to be well settled that the disclosure should be regarded as sufficient.” In re Oelrich, 666 F.2d 578, 581, 212 USPQ 323, 326 (CCPA 1981). Thus, we find claim 24 to be anticipated.

The alkyl amine group can be attached a protein, including collagen, keratin, soy

⁴ Claim 13: “(a) at least one enzyme having transglutaminase activity”

⁵ Claim 13: “(b) at least one active substance having substrate activity for the enzyme”

protein, and wheat protein to form modified active substances. Id., column 3, lines 1-5; column 4, lines 1-5. This disclosure satisfies limitations of claims 15, 16, 17, 25, and 26.

The transglutaminase and substrate can be present in the same composition (columns 18-19, Examples 10-11) or in separate packages (column 14, lines 3-11). When in the same composition, the transglutaminase and substrate would be “applied simultaneously to the keratin fibers,” as recited in claim 21.

In Example 3 of Richardson, the enzyme and substrate are applied for 45 minutes (column 17, line 21) to achieve attachment of the substrate to the skin. This is within the contact time required by claim 23. For this reason, we find this claim to be anticipated by Richardson’s disclosure.

Green '336

Claims 13-15, 23, 24, and 27 are rejected under 35 U.S.C. § 102(b) as being anticipated by Green '336⁶.

To establish anticipation, each element of the claimed invention must be disclosed in the prior art reference. Perricone, 432 F.3d at 1375, 77 USPQ2d at 1325. Green '336 describes a composition containing a transglutaminase and a corneocyte protein. The transglutaminase catalyzes the crosslinking of the corneocyte protein (“substance having substrate activity” in instant claim 13) to the outer layers of skin, hair, or nails to form a protective layer. Green '336, column 3, lines 13-37; column 8, lines 1-8. The composition can be in the form of a shampoo or hair gel. Id., column 8, lines 9-10. When applied to the hair, it would restructure it as required by instant claim

⁶ Green et al. (Green '336), U.S. Pat. No. 5,525,336, issued Jun. 11, 1996.

13. The substrate is a protein (i.e., "corneocyte protein"). Thus, Green '336 discloses the process recited in claims 13 and 15. We also find claim 24 anticipated for the same reasons discussed above for Richardson.

Green '336 discloses that calcium-activated transglutaminase is preferred. Id., column 3, line 25-27. However, in making the composition, Green '336 says that calcium ions are optional, indicating that although the calcium-activated form is preferred, a calcium independent form can be utilized, as well. Id., column 7, line 53. Thus, Green '336 teaches the use of a calcium-independent transglutaminase as recited in claims 14 and 27.

Within one hour, the transglutaminase enzyme crosslinks the substrate to the target. Id., column 8, lines 44-45. Since this time falls within the range recited in claim 23, this dependent claim is anticipated by Green '336.

Green '957

Claims 13, 15, 16, 18-22, 24, and 25 are rejected under 35 U.S.C. § 102(e) as being anticipated by Green '957⁷.

Because this is an anticipation rejection, every element of the claimed subject matter must be identified in the prior art reference. Green '957 teaches attaching agents to tissue with transglutaminase and a linking molecule which is a transglutaminase substrate. Green '957, Abstract. The linking molecule can be joined to an agent, which is then attached to a tissue by the enzymatic action of transglutaminase. An example of an agent is a bulking agent which can be added to

⁷ Green et al. (Green '957), U.S. Pat. No. 6,267,957, issued Jul. 31, 2001.

hair to provide body and strength. Id., column 12, line 66-column 13, line 1. The bulking agent can be a protein, such as collagen and keratin. Id., column, 13, lines 5-11. The composition can be in the form of a hair mousse for thickening hair. Id., column 25, Example 4. These elements meet the requirements of independent process claims 13, and dependent claims 15 and 16.

We have construed claim 24 to include any step in which hair is arranged or styled. This would certainly include applying a “mousse” to the hair, as well as additionally allowing the mousse to dry. Thus, all the elements of claims 24 and 25 are described by Green '957, which therefore anticipates these claims.

The linking molecule used by Green '957 can be glutamine, lysine, and generally aliphatic amines and carboxamides. Id., column 2, line 63-column 3, line 18; column 5, lines 12-15; column 6, lines 45-55; column 7, lines 50-55; and column 8, lines 38-45. A lysine⁸ contains a reactive H₂N-(CH₂)₄ group and glutamine⁹ contains a reactive H₂N-(CO)-CH₂-CH₂ group, meeting the requirements of claims 18-20.

The components can be applied simultaneously to the hair (column 25, Example 4) or successively (column 2, lines 35-41; column 4, lines 19-29). Thus, the limitations of claims 21 and 22 are met.

Summary

The Examiner's rejection of claims 13-27 over prior art is reversed. A new grounds of rejection has been entered under § 102 for claims 13-27.

⁸ Alberts et al., Molecular Biology of the Cell, 132-33 (4th ed., 2002).

⁹ Id.

Time Period for Response

This decision contains a new ground of rejection pursuant to 37 CFR § 41.50(b) (effective September 13, 2004, 69 Fed. Reg. 49960 (August 12, 2004), 1286 Off. Gaz. Pat. Office 21 (September 7, 2004)). 37 CFR § 41.50(b) provides "[a] new ground of rejection pursuant to this paragraph shall not be considered final for judicial review." 37 CFR § 41.50(b) also provides that the appellant, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of the appeal as to the rejected claims:

(1) *Reopen prosecution.* Submit an appropriate amendment of the claims so rejected or new evidence relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the proceeding will be remanded to the examiner. . . .

(2) *Request rehearing.* Request that the proceeding be reheard under § 41.52 by the Board upon the same record. . . .

REVERSED, 37 CFR 41.50(b)

Dann Dorfman Herrell and
Skillman
A Professional Corporation
1601 Market Street
Suite 2400
Philadelphia, PA 19103-2307